

REMARKS

Summary of Office Action

In the Office Action, the Examiner advised that should claims 1, 6 and/or 8 be found allowable, claims 11, 16 and/or 18 would be objected to under 37 CFR 1.75 as being substantial duplicates thereof. The Examiner also objected to claims 1, 11 and 30 due to some informalities. The Examiner rejected claims 1, 6, 8, 11, 16, 18 and 30 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,752,522 to Murphy (hereinafter "Murphy"). No other issues were presented.

Summary of Amendments

Upon entry of the present Amendment, Claims 1, 11 and 30 will have been amended and claim 31 will have been added. Claims 2-5, 7, 9-10, 12-15, 17 and 19-29 remain in withdrawn status. As such, Claims 1-31 remain currently pending.

The amendments to claims 1, 11 and 30 are supported at least by paragraphs [0014], [0027] and [0029] and Figures 3a-3b and 4 of the originally filed specification. Newly added claim 31 is substantially similar to claim 30, but further requires a sensor that can be interposed between the anatomical structures to measure a compressive force exerted therebetween. By the present amendment, Applicant submits that the rejections have been overcome and respectfully requests reconsideration of the outstanding Office Action.

Interview Summary

Applicant wishes to express his sincere appreciation to the Examiner for all of the Examiner's explanations, advice and suggestions during the telephonic interview conducted between the Examiner and Applicant's representatives on August 4, 2008.

During the interview, the Examiner suggested amending the independent claims to recite that the supportive material disposed within the membrane "substantially fills" and defines the

encapsulated volume, as a means of distinguishing over the Murphy reference. This amendment has been made in all of the pending independent claims. Accordingly, Applicant believes that the claims as currently amended clearly distinguish the claimed subject matter from that taught by Murphy.

With regards to the objections to claims 1, 6 and/or 8 as being substantially duplicates of claims 11, 16 and/or 18, the Examiner recommended reciting in claim 11 that the sensor is itself configured to be interposed between the first and second anatomical structures, to differentiate from the instance where the pressure between anatomical structures could be indirectly measured within a single anatomical structure, which instance would be encompassed by claim 1. Applicant is hereby amending claim 11 to more clearly specify that the sensor is interposed between the two structures, according to the Examiner's suggestion.

Applicant respectfully invites the Examiner to call Applicant's representative should he have any other concerns or suggestions regarding the claims. Applicant remains very grateful to the Examiner for all of his help.

Applicant's Response

1. Objection to Claims

The Examiner objected to claims 1, 11 and 30 because the recitation of, for example "the pressure" in line 1 of claim 1 appeared to lack proper antecedent basis (*see, e.g.,* page 2 of Office Action). This objection is respectfully traversed.

Claims 1, 11 and 30 are being amended herewith to recite "a pressure", "an amount of pressure", and "a pressure", respectively, and thus the claims contain proper antecedent basis for the recitation of the pressure therein. Accordingly, the objection to these claims is respectfully requested to be withdrawn.

The Examiner also objected to 1, 6 and/or 8 as being substantially duplicates of claims 11, 16 and/or 18 (*see* Office Action pages 2-3). This objection is respectfully traversed.

Applicant is hereby amending claim 11 to recite that the sensor is “configured to be interposed between said first and second anatomical structures,” to measure the compressive force therebetween, and thus the scope of claim 11 is different than that of claim 1 because the sensor of claim 11 must be capable of taking a *direct* measurement *between* the two anatomical structures, because it is configured to be interposed therebetween, whereas the sensor of claim 1, while capable of taking a direct measurement *within* an anatomical structure, is not specifically recited as being configured to be interposed between two anatomical structures to take such a direct measurement of pressure between the two anatomical structures. Accordingly, claims 11 and 1 are not considered to be substantial duplicates of one another, and Applicant respectfully requests that the provisional objection to the claims be withdrawn.

2. Rejection of Claims 1, 6, 8, 11, 16, 18 and 30 under 35 U.S.C. 102(b) over Murphy

The Examiner rejected claims 1, 6, 8, 11, 16, 18 and 30 under 35 U.S.C. 102(b) as being anticipated by Murphy because the Examiner asserts that Murphy discloses an anatomical pressure-sensing device that meets the limitations of the claim, and in particular refers to column 9, lines 12-35 of Murphy (*see* Office Action pages 3-4). Applicant respectfully traverses this rejection.

Claim 1 as amended recites a device for determining pressure exerted within an anatomical structure comprising, *inter alia*, “a sensor comprising an encapsulated member having (i) a membrane enclosing an encapsulated volume therewithin and (ii) a body of supportive material disposed within the membrane that substantially fills and defines the encapsulated volume” (emphasis added). Thus, claim 1 distinguishes from Murphy in that Murphy does not teach a body of supportive material that occupies a major portion of an encapsulated volume, but instead teaches discrete conductor bands provided about a periphery of a catheter (*see, e.g.,* Figures 5-6 and column 9, lines 13-35). Claims 11, 30 and 31 similarly

recite a body of supportive material that “substantially fills” the encapsulated volume, and thus are also not anticipated by the teachings of Murphy.

Instead, Murphy teaches a catheter for determining the cross-sectional dimensions of body lumens, such as blood vessels (*see, e.g.,* Abstract), in which the measurement of a width of a catheter balloon gives an indication of the diameter of the lumen being measured (*see, e.g.,* column 7, line 66 through column 8, line 12). Murphy teaches that in one embodiment the catheter balloon has bands of conductive material (also called resistors 62) that can be formed of a polymer or elastomeric material having conductive properties, such as polysiloxane foam with graphite impregnation (*see, e.g.,* column 9, lines 12-20 and Figures 5-6). Murphy shows the bands being disposed about a circumference of the balloon (*see, e.g.,* Figures 5-6), and describes how expansion or contraction of the balloon changes the electrical resistance of the bands, which can be measured to calculate the width of the balloon (*see, e.g.,* column 9, lines 21-35).

Thus, while Murphy teaches conductor bands added as sensors about a circumference of a balloon, Murphy does not teach the encapsulated member the claims having the membrane and body of supportive material that substantially fills and defines the encapsulated volume enclosed by the membrane as in claims 1, 11, 30 and 31. Instead, the conductor bands of Murphy are merely strips of material disposed along the periphery of the catheter balloon to help in measuring the diameter of the balloon. Murphy does teach that these conductor bands somehow define and/or substantially fill the encapsulated volume of the balloon. In fact, Murphy teaches that the balloon needs to be “inflated,” for example using a fluid (*see, e.g.,* column 8, lines 12-50), and thus teaches that the internal volume of the balloon is occupied primarily by the fluid such as air used to inflate the balloon, as opposed to a supportive material.

It is furthermore noted that claims 1, 11, 30 and 31 are not obvious over the teachings of Murphy because Murphy does not teach or suggest the desirability of providing a body of supportive material that substantially fills and defines the encapsulated volume. Murphy teaches a balloon catheter that measures dimensions of body lumens by placing the catheter in the lumen

and then inflating the catheter within the lumen until the balloon diameter matches the lumen diameter (*see, e.g.*, Abstract). In contrast, the instantly claimed device comprises a body of supportive and compressible material that maintains the membrane in a generally expanded state when a baseline pressure such as atmospheric pressure is applied (*see, e.g.*, paragraph [0014] and [0026]), and that compresses due upon exertion of pressure by an anatomical structure. Thus, the device as claimed can be understood to be capable of operating in a manner that is almost the reverse of that of the balloon catheter of Murphy, in that the device can be maintained in a baseline “expanded” state, due to the presence of the supportive material, prior to insertion into the anatomical structure, and is allowed to compress under the pressure exerted by the anatomical structure to produce a signal representative of the exerted pressure. Murphy, by comparison, inserts the balloon catheter in an uninflated state, then inflates the balloon catheter in the lumen to obtain the dimension measurements. Murphy does not teach or suggest that a pressure measurement can be obtained via compression of a body of supportive material that substantially fills and defines an encapsulated volume, nor does Murphy teach or suggest any other reasons why such a body of supportive material would be desirable for the balloon catheter, and thus it is considered that one of ordinary skill in the art would not find the claimed device obvious over the inflatable balloon catheter of Murphy.

It is furthermore noted that the instantly claimed device provides significant and non-obvious advantages over the balloon catheter. For example, the claimed device having the body of supportive material provides a “pre-expanded” device that can be inserted into an anatomical structure for pressure measurement without requiring extra inflation. Furthermore, it can be understood that in the embodiment where the supportive material comprises compressive foam, the body of supportive material allows for ready transitioning from an expansive state under reduced pressure to a compressed state under increased pressure, and back to the expansive state when the pressure is released (*see, e.g.*, claim 6), thereby allowing for multiple repeated measurements to be taken without requiring re-inflation of the device. In contrast, the balloon catheter of Murphy, once deflated, may not transition back to the expansive state without a positive pressure of air or fluid flowing back into the catheter (*see, e.g.*, Murphy’s Figure 1).

Thus, the device as claimed can be understood to provide significant and non-obvious advantages over the balloon catheter of Murphy.

Accordingly, claims 1, 11, 30 and 31 are not anticipated by nor obvious over the teachings of Murphy, and the rejection of this claim and the claims depending therefrom is respectfully requested to be withdrawn.

Conclusion

Applicant respectfully submits that each and every pending claim of the present invention meets the requirements for patentability under 35 U.S.C. § 102, and respectfully requests that the Examiner indicate allowance of each and every pending claim of the present invention. In view of the foregoing, it is submitted that none of the references of record, either taken alone or in any proper combination thereof, anticipate or render obvious Applicant's invention as recited in each of Claims 1, 6, 8, 11, 16, 18, 30 and 31. The applied references of record have been discussed and distinguished, while significant claim features of the present invention have been pointed out.

Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested and now believed to be appropriate. To the extent the Examiner has any questions, requires additional information and/or has any suggestions to resolve any outstanding issues that may exist, the Examiner is invited to contact Applicants' counsel at the number listed below.

If any additional fee is required, please charge Deposit Account Number 19-4330.

Respectfully submitted,

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